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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,268	03/01/2004	Leo J. Romanczyk JR.	1010/100US3	3127
32260	7590	12/01/2004	EXAMINER	
NADA JAIN, P.C. 560 White Plains Road, Suite 460 Tarrytown, NY 10591			NUTTER, NATHAN M	
			ART UNIT	PAPER NUMBER
			1711	
DATE MAILED: 12/01/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/790,268	Applicant(s) ROMANCZYK ET AL.	
	Examiner Nathan M. Nutter	Art Unit 1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-78 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 27-78 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>0904</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27-78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27, from which all others depend either directly or indirectly, recites a "pharmaceutical composition comprising a *therapeutically effective amount* of a separated and purified, or synthetic procyanidin oligomer." The claim fails to recite specifically what the composition is to be *effective* to treat. As such, the recitation of *therapeutically effective amount* renders the claim as vague and confusing.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27-78 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As pointed out above, the expression *therapeutically effective amount* is not specific as to any particular malady, disease or condition. Without such knowledge of treatment specifics, the practitioner of ordinary skill would need to perform undue experimentation

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to determine what may be employed as each instance would be separate and distinct to need.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27-47, 55-61 and 67-75 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Tempesta, newly cited.

The reference to Tempesta teaches the use of proanthocyanidine polymers that may comprise the identical "flavenoid 3-ol units linked together through common C(4)-(6) (*sic*) and/or C(4)-C(8)," as herein recited, at the paragraph bridging column 1 to column 2. At column 1 (lines 13-20) the reference teaches the "proanthocyanidin polymers, having 2 to 30 flavenoid units in treating respiratory virus infections," i.e. used in a "therapeutically effective" amount, as recited in instant claims 33, 40, 47, 61 and 73. Note the structures at columns 5-8. The Abstract teaches the use of isolated and synthesized forms of the compounds. The reference teaches the topical administration, intravenous administration, oral and nasal administrations at column 9 (lines 15-18) and the vaginal administration at column 38 (line 45) to column 39 (line 18).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

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F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 27-61 and 67-77 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,747,059. Although the conflicting claims are not identical, they are not patentably distinct from each other because the administration of the oligomers of procyanidin of the instant claims is within the recitations of the patented claims wherein the oligomers are of the same chemical structures having "interflavin linkages 4→6 and/or 4→8." It is irrelevant whether the compounds are isolated or synthesized, the reference teaches both forms, since the composition is identical regardless. Further, the patent claims administration broadly. Any form of administration, oral, rectal, intravenous, vaginal, etc. would be an obvious variant, since "administration," as recited in the claims, includes each of these.

Claims 27-61 and 67-77 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-25 of U.S. Patent No. 6,524,630. Although the conflicting claims are not identical, they are not patentably distinct from each other because the administration of the procyanidin oligomers recited in the instant claims is within the recitations of the patented claims

wherein the oligomers may be of the same chemical structures. It is irrelevant whether the compounds are isolated or synthesized, the reference teaches both forms, since the composition is identical regardless. Further, the patent claims administration broadly. Any form of administration, oral, rectal, intravenous, vaginal, etc. would be an obvious variant, since "administration," as recited in the claims, includes each of these.

Claims 27-78 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 5,712,305. Although the conflicting claims are not identical, they are not patentably distinct from each other because the administration of the procyanidin oligomers recited in the instant claims is within the recitations of the patented claims wherein the oligomers may be of the same chemical structures. It is irrelevant whether the compounds are isolated or synthesized, the reference teaches both forms, since the composition is identical regardless. Further, the patent claims administration broadly. Any form of administration, oral, rectal, intravenous, vaginal, etc. would be an obvious variant, since "administration," as recited in the claims, includes each of these. Since the reference is drawn to the use of an antineoplastic agent, the use of other known agents for this purpose would also be an obvious variant.

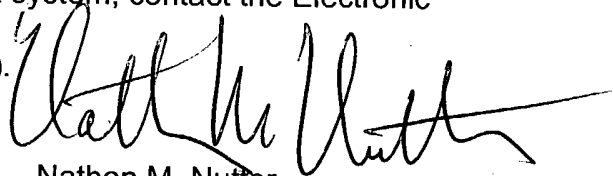
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan M. Nutter whose telephone number is 571-272-1076. The examiner can normally be reached on 9:30 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James J. Seidleck can be reached on 571-272-1078. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nathan M. Nutter
Primary Examiner
Art Unit 1711

nmn

26 November 2004